DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

93614

NOV 1 – 2002

WARNING LETTER

VIA FEDERAL EXPRESS
VIA FACSIMILE

Daniel Hua
President
UPC Medical Supplies, Inc.
Dba United Pacific Company
219 South Raymond Avenue
Alhambra, California 91801

Re: Sacred Crane TDP Lamp, QK-Wide Band Spectrum Apparatus and Millennia Acupuncture Needle

Dear Mr. Hua:

The Food and Drug Administration (FDA) has reviewed promotional material and information on your website at http://www.goacupuncture.com, concerning the Sacred Crane TDP Lamp, QK-Wide Band Spectrum Apparatus, Millennia Acupuncture Needle, and various other products. These products are devices as defined within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Your website states that United Pacific Company (UPC) "has been supplying quality products...to the professional practitioners throughout the United States, in Canada, Europe, South & Central America...ranging from acupuncture supplies, herbs, chiropractic supplies, physical therapeutic products to massage tools."

UPC imports products from Asia and also holds premarket notifications (510(k)s), as follows:

1. K003010 for the Spirit Acupuncture Needle, intended to pierce the skin in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states in which they practice;
2. K001718 for the Millennia Acupuncture Needle, same intended use noted above;
3. K993123 for the QK-Wide Band Spectrum Therapeutic Apparatus, Models CO1A, CO1B, CO1C, CO1D, CO2A and CO2B, intended to use to emit energy in the infrared spectrum to provide topical heating for the purpose of temporarily elevating local tissue temperature. Intended to use for the temporary relief of minor muscle and joint stiffness, temporary relief of muscle strain spasm, temporary increase in local circulation where applied, and the relaxation of muscle;
4. K991503 for the Sacred Crane TDP Lamp, Models CQ-27, CQ-12, and CQ-36, same intended use noted above;
5. K990406 for the Kingli Acupuncture Needle, same intended use noted in #1 and #2 above.

Your website is promoting devices for medical claims that exceed those cleared for the devices, many of which were discussed with you during the 510(k) reviews. At that time, you chose to remove the claims from the labeling rather than submit the information required to support a 510(k) clearance. The claims that exceed those cleared for the devices include:

Claims for the CQ-27 TDP Infrared Lamp representing that, "[T]he TDP Far-Infrared Therapeutic Lamp...can provide focused deep heating in therapeutic treatments such as those to increase blood circulation and metabolism. Clinical studies have shown some of the following benefits: decreased inflammation and edema from soft tissue injuries; relief of pain, including arthritis pain; promotion of

circulation and healing; healing of skin disorders; and balancing of the nervous system – Alternative Medicine Magazine," and "[T]he TDP Lamp features a round plate coated with a proprietary mineral formation consisting of 33 elements essential to the human body. When activated...this mineral plate emits a special band of electromagnetic waves...that coincide with the wavelength and intensity of the electromagnetic waves released by a human body and consequently absorbed by the body (so-called selective absorption). This absorbed electromagnetic energy has been found to yield healing effects on the human body by promoting local blood circulation, metabolism and help strengthen immune system as well as alleviate pain on the body."

Claims for Millennia Acupuncture needles that state the needles are proven "for smooth, painless insertion," and that "electrically conductive metal handles achieve best result of maximum Qi, electro-acupuncture and moxa therapy." The Office of Device Evaluation (ODE) has cleared only silicone-lubricated acupuncture needles with a claim "painless." The Millennia needles do not have a silicone lubricant, therefore you would need to submit data to support the claim that these needles are "painless."

Claims for the QK-Wide Band Spectrum Therapeutic Apparatus (3rd Generation TDP Lamp) that promotes it as an apparatus that "was invented on the theoretical basis that there exists material and energy metabolism all the time inside the body which maintains the normal performance of physiological and biochemical functions, and that cells are activated by absorbing light quantum." Various "Scope of Applications" are listed, including "Blood Circulatory System; Dermal System; Digestive System; Disease Prevention; Endocrine System; Fatigue; Genito-urinary System; Immunity Deficiency; Inflammation; Nervous System; Opthalmopathy; Otorhinolangophaty; Respiratory System; Sport Injury; Stomatopathy; Surgical Complications."

The claims discussed above significantly modify the intended use(s) of the devices, as defined under 21 CFR 801.4, and would require the submission and prior clearance of a new 510(k) as required by 21 CFR 897.81(a)(3)(ii). Continued promotion of the devices for these claims will cause your devices to be misbranded and adulterated under sections 502(o) and 501(f)(1)(B) of the Act, respectively.

The following devices are also being promoted on your website with claims that have not been reviewed or cleared via a premarket notification or premarket approval application (PMA). The claims include:

Claims on your website for the Pro Massager – Gi Gong Tech Machine (http://www.goacupuncture.com/cgi-bin/ie/ProductDetail.pl?SkuNo=S-01) include: "In the U.S, the Chi device is offered as a professional massager effective for pain management, relaxation, and local blood circulation. It may also be used by acupuncturists and chiropractors as a means to add or reinforce "chi" in the body. It is especially effective when used on acu-points or in conjunction with acupuncture or acupressure treatments. The Pro Massager is an alternative to drug therapy for those who suffer from chronic pain, fatigue and injuries. It is helpful to the relief of stress, local blood circulation, and nervous system, reduction of swelling, relaxed muscles; and improve the healing process." There is a Question & Answer section that states that the waves generated by the Pro Massager have been known in China to increase Chi, the body energy that "will help the body and promotes the vitality." Qi Gong Massager devices are cleared as a therapeutic vibrator intended for the relief of minor aches and pains, increased local circulation, and muscle relaxation.

Claims for the Qi (Chi) Machine include statements that the Machine is "For your Vigor & Blood Circulation" and claims to be "helpful to the following conditions. Hemorrhoids; Obesity; Cosmetic Enhancement; Constipation; Insomnia; Coronary Heart Disease; Hypertension; Shoulder & Back Pain; Chronic Gastritis; Cervical Spondylitis; Tracheitis; Cervical Spondylitis, Pain in Waist and Legs; Apoplexy (recovering from) and Diabetes; Prostate Hyperplasia, Menopausal Syndrome; Lack of Exercise, Extended Sitting."

Claims for the Stimplus II Acupoint Locator & Stimulation device include that it "locate[s] acupoints and then stimulate away the pain electronically at the touch of a button without needles. Acupoints are detected with sound and light...Stimplus also emits a low pitch sound while it moves to an acupoint. The Stimplus is ideal for pain management, sports injuries, smoking severance, eating disorders, stress & insomnia."

Claims for the Gua Sha Tool state that it is "a virtually traditional Chinese system of promoting Qi and blood circulation to remove toxins and stagnant fluids for the rapid relief of pain and discomfort." The Bio-spectrum Device (Infrared Lamp) is promoted as "improving...metabolism, helping immune system, regulating nerve system."

Products distributed in the United States may only be promoted for those uses for which FDA has cleared or approved them. As noted earlier, continued promotion of any of these devices for these claims will cause your devices to be misbranded and adulterated under sections 502(0) and 501(f)(1)(B) of the Act, respectively. Please note that statements implying that the devices are FDA-approved are misleading. Only devices that have an approved PMA are considered approved by the FDA.

This letter is not intended to be an all-inclusive list of deficiencies associated with the products you are promoting. It is your responsibility to ensure adherence to each requirement of the Act and Federal regulations. The specific violations noted in this letter may represent practices used in other promotion or advertising materials used by your firm. You are responsible for investigating and reviewing these materials to assure compliance with applicable regulations.

You should take prompt action to correct these violations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office, in writing, within 15 working days of receipt of this letter, outlining the specific steps you have taken to correct the cited violations. Your response should also include all steps being taken to address misleading information currently in the market place, and actions to prevent similar violations in the future. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Ms. Patricia L. Jahnes, Consumer Safety Officer, Promotion and Advertising Policy Staff (HFZ-300), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's Los Angeles District Office. Please send a copy of your response to the District Director, Food and Drug Administration, Los Angeles District Office (HFR-PA200), 19900 MacArthur, Suite 300, Irvine, California 92612.

Sincerely yours,

Philip J. Frappaolo
Acting Director
Office of Compliance
Center for Devices and
Radiological Health